

## CLAIMS:

1. A catheter assembly comprising:  
a catheter, the catheter comprising a catheter shaft and a balloon positioned thereon; and  
5 a rotatable sheath, the rotatable sheath rotatably disposed about at least a portion of the catheter, the rotatable sheath having a first portion inner diameter and a second portion inner diameter, the first portion inner diameter being different than the second portion inner diameter.
2. The catheter assembly of claim 1 further comprising a guidewire housing, the  
10 guidewire housing defining a guidewire lumen for passage of a guidewire therethrough, at least a portion of the guidewire housing being engaged to at least a proximal portion of the rotatable sheath.
3. The catheter assembly of claim 2 further comprising a stent, the stent being disposed about at least a portion of the rotatable sheath.
- 15 4. The catheter assembly of claim 3 wherein at least a portion of the stent is disposed about at least a portion of the guidewire housing.
5. The catheter assembly of claim 1 wherein the rotatable sheath comprises a first portion, a second portion and a third portion, at least the second portion of the rotatable sheath being disposed about the balloon and being positioned between the first portion and  
20 the third portion of the rotatable sheath, the first portion defining the first portion inner diameter and the second end portion defining the second portion inner diameter, the first portion inner diameter being less than the second portion inner diameter.
6. The catheter assembly of claim 5 wherein the rotatable sheath comprises a length, the second portion inner diameter being substantially constant along the length of the second  
25 portion.
7. The catheter assembly of claim 6 wherein the first portion inner diameter tapered along the length of the first portion.

8. The catheter assembly of claim 6 wherein the third portion defines a third portion inner diameter, the third portion inner diameter being less than the second portion inner diameter.

9. The catheter assembly of claim 8 wherein the third portion inner diameter is tapered  
5 along the length of the third portion.

10 The catheter assembly of claim 1 wherein the rotatable sheath comprises a wall thickness and a length, at any point along the length the wall thickness comprises an alternating pattern of thicker and thinner regions, the first portion inner diameter being defined by at least one thinner region of the wall thickness, the second portion inner  
10 diameter being defined by at least one thicker region of the wall thickness.

11. The catheter assembly of claim 10 wherein only a portion of each thicker region of the rotatable sheath is in rotatable contact with the catheter.

12. The catheter assembly of claim 1 wherein the rotatable sheath comprises at least one radiopaque band of material.

15 13. The catheter assembly of claim 4 wherein the rotatable sheath comprises at least one radiopaque band of material, the at least one radiopaque band of material positioned to underlie at least one portion of the stent.

14. The catheter assembly of claim 13 wherein the at least one radiopaque band of material is adjacent to a distal end portion of the secondary guidewire housing.

20 15. The catheter assembly of claim 1 further comprising a stent, the stent being disposed about at least a portion of the rotatable sheath, the stent comprising a plurality of interconnected stent members wherein adjacent members define cell openings.

16. The catheter assembly of claim 15 wherein the rotatable sheath comprises an inner surface, an outer surface and a thickness therebetween, the inner surface of the sheath wall  
25 being rotatably disposed about the catheter, the stent being disposed about at least a portion of the outer surface, the thickness of the rotatable sheath defines at least one guidewire lumen therethrough, the at least one guidewire lumen having a first lumen opening and a second lumen opening, the first lumen opening being defined by the thickness at a first end of the rotatable sheath, the second lumen opening being defined by the outer surface of the  
30 rotatable sheath.

17. The catheter assembly of claim 16 wherein the second lumen opening is substantially aligned with a cell opening of the stent.

18. The catheter assembly of claim 16 further comprising a guidewire, the guidewire extending through the at least one guidewire lumen from the first lumen opening through the  
5 second lumen opening and through the cell opening of the stent.

19. The catheter assembly of claim 18 wherein the thickness of the rotatable sheath defines a plurality of guidewire lumens, each guidewire lumen having a different first lumen opening and a different second lumen opening.

20. The catheter assembly of claim 19 wherein each guidewire lumen has a different  
10 length.

21. The catheter assembly of claim 15 wherein the rotatable sheath comprises a first end portion, a second end portion and an intermediate portion therebetween, the stent being disposed about the intermediate portion of the rotatable sheath, the first end portion having a first end portion outer diameter, the second end portion having a second end portion outer  
15 diameter, the intermediate portion having an intermediate portion outer diameter, the stent having a stent outer diameter, at least one of the first end portion outer diameter and the second end portion outer diameter being at least as great as the stent outer diameter.

22. The catheter assembly of claim 21 wherein the first end portion outer diameter and the second end portion outer diameter are substantially equal to the stent outer diameter.

20 23. The catheter assembly of claim 21 wherein the first end portion outer diameter and the second end portion outer diameter are substantially greater than the stent outer diameter.

24. The catheter assembly of claim 15 wherein at least a portion of the stent is coated with at least one therapeutic agent.

25. The catheter assembly of claim 24 wherein the at least one therapeutic agent is at  
25 least one non-genetic therapeutic agent selected from at least one member of the group consisting of: anti-thrombogenic agents such as heparin, heparin derivatives, urokinase, and PPACK (dextrophenylalanine proline arginine chloromethylketone); anti-proliferative agents such as enoxaprin, angiopeptin, monoclonal antibodies capable of blocking smooth muscle cell proliferation, hirudin, and acetylsalicylic acid; anti-inflammatory agents such as  
30 dexamethasone, prednisolone, corticosterone, budesonide, estrogen, sulfasalazine, and

mesalamine; antineoplastic/antiproliferative/anti-miotic agents such as paclitaxel, 5-fluorouracil, cisplatin, vinblastine, vincristine, epothilones, endostatin, angiostatin and thymidine kinase inhibitors; anesthetic agents such as lidocaine, bupivacaine and ropivacaine; anti-coagulants such as D-Phe-Pro-Arg chloromethyl keton, an RGD peptide-containing  
5 compound, heparin, antithrombin compounds, platelet receptor antagonists, anti-thrombin antibodies, anti-platelet receptor antibodies, aspirin, prostaglandin inhibitors, platelet inhibitors and tick antiplatelet peptides; vascular cell growth promoters such as growth factor inhibitors, growth factor receptor antagonists, transcriptional activators, and translational promoters, vascular cell growth inhibitors such as growth factor inhibitors,  
10 growth factor receptor antagonists, transcriptional repressors, translational repressors, replication inhibitors, inhibitory antibodies, antibodies directed against growth factors, bifunctional molecules consisting of a growth factor and a cytotoxin; bifunctional molecules consisting of an antibody and a cytotoxin; cholesterol-lowering agents; vasodilating agents; and agents which interfere with endogenous vasoactive mechanisms, and any combinations  
15 thereof.

26. The catheter assembly of claim 24 wherein the at least one therapeutic agent is at least one genetic therapeutic agent selected from at least one member of the group consisting of: anti-sense DNA and RNA; DNA coding for anti-sense RNA, tRNA or rRNA to replace defective or deficient endogenous molecules; angiogenic factors including growth  
20 factors such as acidic and basic fibroblast growth factors, vascular endothelial growth factor, epidermal growth factor, transforming growth factor  $\alpha$  and  $\beta$ , platelet-derived endothelial growth factor, platelet-derived growth factor, tumor necrosis factor  $\alpha$ , hepatocyte growth factor and insulin like growth factor; cell cycle inhibitors including CD inhibitors, thymidine kinase ("TK") and other agents useful for interfering with cell proliferation; at least one of  
25 the family of bone morphogenic proteins ("BMP's") such as BMP-2, BMP-3, BMP-4, BMP-5, BMP-6 (Vgr-1), BMP-7 (OP-1), BMP-8, BMP-9, BMP-10, BMP-11, BMP-12, BMP-13, BMP-14, BMP-15, and BMP-16. Any of BMP-2, BMP-3, BMP-4, BMP-5, BMP-6 and BMP-7; dimeric proteins such as homodimers, heterodimers, or combinations thereof, alone or together with other molecules; molecules capable of inducing an upstream  
30 or downstream effect of a BMP such as "hedgehog" proteins, or the DNA's encoding them

and any combinations thereof.

27. The catheter assembly of claim 24 wherein the at least one therapeutic agent is at least one type of cellular material selected from at least one member of the group consisting of: cells of human origin (autologous or allogeneic); cells of non-human origin (xenogeneic) and any combination thereof.

28. The catheter assembly of claim 27 wherein the cellular material is selected from at least one member of the group consisting of: side population cells; lineage negative cells; lineage negative CD34<sup>-</sup> cells; lineage negative CD34<sup>+</sup> cells; lineage negative cKit<sup>+</sup> cells; mesenchymal stem cells; cord blood cells; cardiac or other tissue derived stem cells; whole bone marrow; bone marrow mononuclear cells; endothelial progenitor cells; satellite cells; muscle derived cells; go cells; endothelial cells; adult cardiomyocytes; fibroblasts; smooth muscle cells; cultures of mesenchymal stem cells with 5-aza forces differentiation into cardiomyocytes; adult cardiac fibroblasts + 5-aza; genetically modified cells; tissue engineered grafts; MyoD scar fibroblasts; Pacing cells; embryonic stem cell clones; embryonic stem cells; fetal or neonatal cells; immunologically masked cells; tissue engineered grafts; genetically modified cells; teratoma derived cells and any combinations thereof.

29. The catheter assembly of claim 24 wherein the at least one therapeutic agent comprises at least one polymer coating, the at least one coating selected from at least one member of the group consisting of: polycarboxylic acids; cellulosic polymers, including cellulose acetate and cellulose nitrate; gelatin; polyvinylpyrrolidone; cross-linked polyvinylpyrrolidone; polyanhydrides including maleic anhydride polymers; polyamides; polyvinyl alcohols; copolymers of vinyl monomers such as EVA; polyvinyl ethers; polyvinyl aromatics; polyethylene oxides; glycosaminoglycans; polysaccharides; polyesters including polyethylene terephthalate; polyacrylamides; polyethers; polyether sulfone; polycarbonate; polyalkylenes including polypropylene, polyethylene and high molecular weight polyethylene; halogenated polyalkylenes including polytetrafluoroethylene; polyurethanes; polyorthoesters; proteins; polypeptides; silicones; siloxane polymers; polylactic acid; polyglycolic acid; polycaprolactone; polyhydroxybutyrate valerate and blends and

- copolymers thereof; coatings from polymer dispersions such as polyurethane dispersions (BAYHDROL<sup>®</sup>, etc.), fibrin, collagen and derivatives thereof; polysaccharides such as celluloses, starches, dextrans, alginates and derivatives; hyaluronic acid; squalene emulsions; polyacrylic acid, a copolymer of polylactic acid and polycaprolactone; medical-grade
- 5 biodegradable materials such as PGA-TMC, Tyrosine-Derived Polycarbonates and arylates; polycaprolactone co butyl acrylate and other co polymers; Poly-L-lactic acid blends with DL-Lactic Acid; Poly(lactic acid-co-glycolic acid); polycaprolactone co PLA; polycaprolactone co butyl acrylate and other copolymers; Tyrosine-Derived Polycarbonates and arylate; poly amino acid; polyphosphazenes; polyiminocarbonates;
- 10 polydimethyltrimethylcarbonates; biodegradable CA/PO<sub>4</sub> 's; cyanoacrylate; 50/50 DLPLG; polydioxanone; polypropylene fumarate; polydepsipeptides; macromolecules such as chitosan and Hydroxylpropylmethylcellulose; surface erodible material; maleic anhydride copolymers; zinc-calcium phosphate; amorphous polyanhydrides; sugar; carbohydrate; gelatin; biodegradable polymers; and polymers dissolvable in bodily fluids; A block
- 15 copolymers; B block copolymers and any combinations thereof.
30. The catheter assembly of claim 1 further comprising a lubricious coating, the lubricious coating positioned between at least a portion of the rotatable sheath and the catheter shaft.
31. The catheter assembly of claim 1 wherein the rotatable sheath is at least partially
- 20 constructed from a hydrophilic polymer material.
32. The catheter assembly of claim 1 wherein the rotatable sheath is at least partially constructed from a tecophilic material.
33. The catheter assembly of claim 1 wherein the rotatable sheath is at least partially constructed from a first material and a second material.
- 25 34. The catheter assembly of claim 33 wherein the rotatable sheath is at least partially constructed from at least one material of the group consisting of: hydrophilic polyurethanes, aromatic polyurethanes, polycarbonate base aliphatic polyurethanes, engineering polyurethane, elastomeric polyamides, block polyamide/ethers, polyether block amide, silicones, polyether-ester, polyester, polyester elastomer, polyethylene, polyamide, high-

density polyethylene, polyetheretherketone, polyimide, polyetherimide, liquid crystal polymers, acetal, and any combination thereof.

35. The catheter assembly of claim 33 wherein the first material is a polymer matrix and the second material is at least one distinct member of reinforcing material at least partially supported within the polymer matrix.

36. The catheter assembly of claim 35 wherein polymer matrix is selected from at least one material from the group consisting of: hydrophilic polyurethanes, aromatic polyurethanes, polycarbonate base aliphatic polyurethanes, engineering polyurethane, elastomeric polyamides, block polyamide/ethers, polyether block amide, silicones, polyether-ester, polyester, polyester elastomer, polyethylene and any combination thereof.

37. The catheter assembly of claim 35 wherein the reinforcing material is selected from at least one material of the group consisting of polyamide, polyethylene, high-density polyethylene, polyetheretherketone, polyimide, polyetherimide, liquid crystal polymers, acetal, and any combination thereof.

38. The catheter assembly of claim 1 wherein the a rotatable sheath has a length substantially less than the length of the catheter.

39. A catheter assembly comprising:  
     a catheter, the catheter comprising a catheter shaft and a balloon positioned thereon;  
     a rotatable sheath, the rotatable sheath rotatably disposed about at least a portion of the catheter shaft adjacent to the balloon;  
     a stent the stent rotatably disposed about at least a portion of the balloon; and  
     at least one stent engagement member, the at least one stent engagement member being actuatable from an engaged position to a released position, in the engaged position the at least one stent engagement member extending from the rotatable sheath to engage the stent, in the released position the stent being released from the at least one engagement member.

40. The catheter assembly of claim 39 further comprising a guidewire housing, the guidewire housing defining a guidewire lumen for passage of a guidewire therethrough, at least a portion of the guidewire housing being engaged to at least a portion of the rotatable

sheath, at least a portion of the stent disposed about a distal portion of the guidewire housing.

41. The catheter assembly of claim 39 wherein at least a portion of the at least one stent engagement member is bio-absorbable.

5 42. The catheter assembly of claim 39 wherein the at least one stent engagement member is mechanically actuatable.

43. The catheter assembly of claim 39 wherein the at least one stent engagement member is at least partially constructed from an electro-active polymer.

10 44. The catheter assembly of claim 43 wherein the at least one stent engagement member is electrically actuatable.

45. The catheter assembly of claim 39 wherein the rotatable sheath is positioned proximally adjacent to the balloon.

15 46. The catheter assembly of claim 45 wherein further comprising a hub, the hub having an outer diameter greater than an inner diameter of the rotatable sheath, the hub positioned proximally adjacent to the rotatable sheath.

47. A method of forming a rotatable sheath assembly for use in a stent delivery system comprising:

providing a tubular member, the tubular member having a wall which defines a tubular member inner diameter;

20 disposing the first tubular member about a first support mandrel, the first support mandrel having a first support mandrel outer diameter, the first support mandrel outer diameter being substantially less than the tubular member inner diameter;

pinching a portion of the wall of the tubular member together along a seam, a first portion of the tubular member on one side of the seam forming a primary lumen and a  
25 second portion of the tubular member on the other side of the seam forming a secondary lumen, the first support mandrel being positioned within the primary lumen, the primary lumen defining a primary lumen diameter, the secondary lumen defining a secondary lumen diameter; and

30 removing a predetermined area of the wall to form an opening in communication with the secondary lumen.



48. The method of forming a rotatable sheath assembly of claim 47 further comprising the steps of:

positioning a second support mandrel through the secondary guidewire lumen, the secondary support mandrel having a secondary support mandrel outer diameter;

5 heat setting the tubular member such that the primary lumen diameter is at least as great as the first support mandrel outer diameter and the secondary lumen is at least as great as the secondary support mandrel outer diameter;

removing the first support mandrel and the second support mandrel from the tubular member.

10 49. The method of forming a rotatable sheath assembly of claim 48 wherein the second portion of the tubular member comprises a proximal region and a distal region, the proximal region being proximal to the opening and the distal region being distal to the opening, the method further comprising the steps of:

15 folding the distal region of the second portion about the first portion, such that the secondary lumen extends through the opening and through the proximal region of the second portion of the tubular member.

50. The method of forming a rotatable sheath assembly of claim 48 wherein the second portion of the tubular member comprises a proximal region and a distal region, the proximal region being proximal to the opening and the distal region being distal to the opening, the method further comprising the steps of:

20 removing the distal region of the second portion along the seam, such that the secondary lumen extends through the opening and through the proximal region of the second portion of the tubular member.